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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,712	12/12/2000	D. Wade Walke	LEX-0109-USA	5587

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/735,712	WALKE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet.*

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-8.*

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because:

I. Claim rejection under 35 U.S.C. § 101

The rejection of Claims 1-4 under 35 U.S.C. § 101 stands. The newly added claims 5-8 are also rejected under 35 U.S.C. § 101.The instant specification fails to disclose sufficient information on the specific functions of the protein with the deduced amino acid sequence encoded by the claimed nucleic acid and thus fails to satisfy the utility requirement set forth under 35 U.S.C. § 101.

Applicants argue that the amino acid sequence deduced from the claimed nucleic acid sequence is related to CD20 or IgE receptor like molecules and thus the claimed invention has a well-established utility. This has been fully considered but is not deemed to be persuasive because 35 U.S.C.101 requires disclosure of a specific, substantial, and credible utility, or a well-established utility. Such a patentable utility has to be a "real world " context of use which does not require significant further research. The instant disclosure asserts that the claimed nucleic acid encodes a CD20 or IgE receptor like molecule. Nonetheless, the disclosure fails to disclose the biological functions of the protein encoded by the claimed nucleic acid. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? Nature Genetics 18:313-318,1998). In the case of GPCRs, Members of the GPCRs do share overall sequence homology, nonetheless, sequence similarity itself does not necessarily indicate that a protein is a functional GPCR. There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al. G-protein-coupled receptors, JBC, 273:17299-17302, 1998).

Since it is unclear whether the protein encoded by the claimed nucleic acid is a CD20 or IgE receptor like molecule, its function obviously is unknown and remain to be determined.Therefore, the information provided or "predicted" based upon sequence homology can only be used as guidance in determining functions of a molecule by experiments. Any functions predicted based upon the sequence homology will have to be confirmed ultimately by bench work. Such confirmation whether the claimed nucleic acid encodes a functional CD20 or IgE receptor like molecule requires undue experimentation. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion".

Applicants argue that the instant disclosure provides a patentable utility for the claimed invention citing the "device" case law. This has been fully considered but is not deemed to be persuasive because the "device" case law deals with "inopertiveness" under 101 (pertains to perpetual motion machines, for example). The claimed invention in the instant case is drawn to an isolated nucleic acid, not a device and the instant rejection under 35USC101 is not directed to inoperativeness, but to a lack of patentable utility of the claimed nucleic acid. Thus, applicants' argument citing a case law regarding a device is irrelevant to the instant case.

Applicants further argue that the claimed nucleotide sequence shares a high degree of sequence homology with sequences present in GenBank which have been annotated as gene family encoding CD20 or IgE receptor like molecules (Liang and Tedder, GenBank, Accession No. AF237907, April 17, 2001; Ishibashi et al, GenBank, Accession No. AB013103, Mar 20, 2001) and thus it is sufficient to justify that the protein encoded by the claimed nucleic acid is a CD20 or IgE receptor like molecule. This has been fully considered but is not deemed to be persuasive because the annotation for the published sequence is also based upon sequence homology and there is no sufficient information that indicates the published sequences encode truly functional CD20 or IgE receptor like molecules (Liand and Tedder, Genomics 72:119-127, 2001; Ishibashi et al, Gene, 264:87-93, 2001). As stated by Ishibashi et al. in the Abstract, the physiological significance of the gene family is currently unclear.

II. Claim Rejections Under 35 U. S. C. 112, 1st Paragraph
Claims 1-8 are rejected under 35 U. S. C. 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention.

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set for the above.

III. Claim Rejection Under 35 U. S. C. 112, second Paragraph
The rejection of Claim 2 under 35 U.S.C. 112, second paragraph remains. The amendment of the claim by adding washing condition does not overcome the rejetion because the highly stringent conditions comprises wash conditions and thus the claim reads on lowering stringency before ending the hybridization.